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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

APOTEX INC., Plaintiff, v. AMARIN PHARMA, INC., AMARIN PHARMACEUTICALS IRELAND LIMITED, AMARIN CORPORATION PLC Defendants.	Docket No.

COMPLAINT

Plaintiff Apotex Inc. ("Apotex") brings this antitrust, breach of contract and declaratory judgment suit against Amarin Pharma, Inc., Amarin Pharmaceuticals Ireland Limited, and Amarin Corporation plc (collectively "Amarin" or "Defendants"), by and through its counsel, and alleges as follows:

INTRODUCTION

1. This is first an antitrust action under the Sherman Act and New Jersey law arising out of Amarin's anticompetitive conduct to delay and prevent generic competition to its branded Vascepa (icosapent ethyl) product. For over a decade, Amarin has engaged in a calculated anticompetitive scheme, whereby it executed exclusive, or de facto exclusive, agreements with suppliers to lock up the supply of Vascepa's active pharmaceutical ingredient ("API"), icosapent ethyl, in order to freeze its generic competitors out of the market and deprive consumers of affordable medication.

2. Vascepa is a prescription drug product used, among other things, to lower harmful triglycerides, a type of lipid. As Amarin's only marketed product approved by the U.S. Food and Drug Administration ("FDA"), Vascepa sales are the near exclusive driver of the company's success.

3. For Amarin, it is Vascepa or bust. The company has no other products and no meaningful pipeline behind Vascepa.[1] Knowing that generic entry would mean an immediate loss of nearly all its Vascepa sales, and a reversal of its meteoric revenue growth, Amarin made concerted illegal efforts to protect its product from generic competition through a series of exclusive, or de facto exclusive, agreements with different API suppliers. In exchange for agreeing to purchase certain minimum amounts, API suppliers agreed not to supply API to any other companies—including Apotex or any other generic manufacturer. What is more, under some

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[1] *See* Leila Hawkins, *Pharma IQ speaks to Amarin about its unique approach to treating cardiovascular disease and having a country-by-country strategy* (Nov. 30, 2022), https://www.pharma-iq.com/market-access/interviews/pharma-company-with-a-build-as-you-go-approach (quoting Laurent Abuaf, the "SVP and President for Europe at Amarin" as stating that Amarin is "a one-product company, which means it is a high risk for [Amarin]"); Christopher Crocker, *Amarin's Vascepa: Reject the Noise and Accept the Facts*, Seeking Alpha (Nov. 28, 2018 9:30 AM ET), https://seekingalpha.com/article/4225047-amarins-vascepa-reject-noise-and-accept-facts (after the Vascepa clinical studies were over, Amarin's then-"CEO John Thero said Amarin plans to completely cut R&D").

(if not all) of the agreements, Amarin agreed to make a cash payment to maintain exclusivity in the event that Amarin was not able to satisfy the minimum purchase requirement. This scheme prevented the API supplier in question from contracting with another company, like Apotex, despite the API supplier having available, unused capacity.

4. There is no legitimate business reason for Amarin's conduct. Amarin's exclusive agreements with these API suppliers can only be explained as a systematic effort to ensure that no other company could manufacture the generic version of its product, or, even if a generic manufacturer could cobble together enough API supply to launch, that it would only be able to supply a tiny fraction of the market demand.

5. Contracting for exclusivity with numerous API suppliers for a single product is inconsistent with the well-established industry practice of drug manufacturers having only one or two API suppliers (even if more are available) because of the considerable cost associated with acquiring and storing API as well as the increased potential for quality issues if sourcing API from multiple suppliers. Deviating from industry practice is especially unusual for a drug that has had no known supply issues. Amarin has even publicly touted its vast API supply.[2]

6. Indeed, Amarin has admitted that the purpose of its unique supply arrangements is to protect itself from competition. Its CEO made Amarin's anticompetitive goals explicit: "Amarin's goal [is] to protect the commercial potential of Vascepa to beyond 2030 through a combination of patent protection, regulatory exclusivity, trade secrets and by taking advantage of manufacturing barriers to entry."[3]

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[2] Amarin Corp. plc, *Amarin Provides Preliminary 2017 Results and Provides 2018 Outlook* (Jan. 4, 2018), https://amarincorp.gcs-web.com/static-files/ee8af8cb-e84a-44cb-ae6c-800b16ac88dc.

[3] Amarin Corp., *Amarin Announces Approval of Supplemental New Drug Application for Chemport as Additional Vascepa(R) Active Pharmaceutical Ingredient Supplier* (Apr. 18, 2013), https://amarincorp.gcs-web.com/static-files/c822b3d2-72d5-49e2-a3a0-90d92854fb3f (emphases added).

7. But Amarin has not simply taken advantage of those "barriers to entry"; it created them. And those barriers have harmed, and continue to harm, Apotex and consumers.

8. Amarin began marketing Vascepa in 2012 and enjoyed a period of market exclusivity for the following eight years. During that time, Apotex and other generic manufacturers prepared to launch generic equivalents to Vascepa as soon as they received FDA approval for their products.

9. On June 16, 2020, Apotex executed a Settlement and License Agreement with Amarin (the "Settlement Agreement" or "Agreement") as part of its efforts to clear the practical hurdles to its generic launch. In the Settlement Agreement, Amarin agreed to forego its alleged patent infringement claims against Apotex and granted Apotex license to launch its generic product upon the earlier of August 9, 2029 or the occurrence of certain specified events, including if the Federal Circuit denied Amarin's then-pending appeal of the District of Nevada's decision invalidating its Vascepa patents[4] ("Nevada Litigation"). Amarin explicitly agreed [redacted]

10. Yet that is exactly what Amarin did. Consistent with its longstanding anticompetitive scheme, it locked up the supply of Apotex's API-supplier, K.D. Pharma Bexbach GmbH ("KD Pharma"). When Amarin learned of Apotex's, and other generic suppliers', intent to obtain API from KD Pharma, it rushed to blockade that supply. To that end, in 2017, Amarin entered into a supply agreement requiring KD Pharma to dedicate its entire API capacity to Amarin, notwithstanding that it had no need for that additional supply.

11. On September 3, 2020, the Federal Circuit summarily affirmed the District Court's judgment in the Nevada Litigation. Accordingly, pursuant to the Settlement Agreement, Apotex

[4] *Amarin Pharma, Inc. v. Hikma Pharm. USA*, 449 F. Supp. 3d 967 (D. Nev. 2020).

should have been cleared to market its product at least as soon as when it received FDA approval, which was granted on June 30, 2021. Earlier, during the regulatory review of Apotex's product, [redacted] The reason for KD Pharma's conduct is now clear: Amarin's sweeping and highly successful effort in securing an exclusive, or de facto exclusive, agreement with KD Pharma (along with other API suppliers), which precluded it from supplying generic manufacturers. When [redacted]

12. Due to KD Pharma's unexpected refusal to comply with the supply agreement, [redacted], which delayed its generic launch from June 2021—when it received FDA approval to launch using KD Pharma's API—to December 2021—when it received supplemental approval to launch [redacted].

13. Section 5.2 of the Settlement Agreement [redacted] Yet, in direct breach of that provision, Amarin's anticompetitive actions delayed and negatively impacted the scope and scale of Apotex's generic launch, causing it to incur many millions of dollars of damages in the form of lost profits beginning from *at latest* June 2021. Apotex has continued to suffer damages even following its launch due to the delays and negative market impacts to Apotex's share of the market resulting from Apotex's inability to obtain its intended level of supply from its intended supplier in a market beginning to undergo some generic entry.

14. Apotex now asserts claims for breach of contract, and under federal and state antitrust law, seeking to recover those damages, treble damages and attorneys' fees and costs, as well as an order requiring Amarin to cease its unlawful conduct.

15. In addition to seeking relief for Amarin's breach of contract and anticompetitive conduct, Apotex seeks a declaratory judgment that the Settlement Agreement's limited provisions relating to mutual release and covenants not to sue do not apply to, and as a matter of law do not preclude, the claims Apotex asserts against Amarin here.

PARTIES

16. Plaintiff Apotex Inc. is a company organized and existing under the laws of Canada, with its principal place of business at 150 Signet Drive, Toronto, Canada MK9L 1T9.

17. On information and belief, Defendant Amarin Pharma, Inc. is a company organized and existing under the laws of Delaware with its principal place of business at 440 Route 22, Suite 330, Bridgewater, New Jersey 08870.

18. On information and belief, Defendant Amarin Pharmaceuticals Ireland Limited is a company incorporated under the laws of Ireland with registered offices at 88 Harcourt Street, Dublin 2, Dublin, Ireland.

19. On information and belief, Defendant Amarin Corporation plc is a company incorporated under the laws of England and Wales with principal executive offices at 77 Sir John Rogerson's Quay, Block C, Grand Canal Docklands, Dublin 2, Ireland.

JURISDICTION AND VENUE

20. Apotex's antitrust claims arise under the antitrust laws of the United States, including Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, Sections 4 and 16 of the

Clayton Act, 15 U.S.C. §§ 15(a) and 26, the New Jersey Antitrust Act, N.J. Stat. § 56:9, and New Jersey common law. Apotex asserts its breach of contract claim under Delaware common law and its declaratory judgment claims under the Declaratory Judgment Act, 28 U.S.C. § 2201.

21. The actions complained of have occurred in and substantially affected interstate commerce. Specifically, Amarin is engaged in interstate commerce and in activities substantially affecting interstate commerce. Amarin's conduct alleged herein has a substantial effect on interstate commerce. Amarin purchases icosapent ethyl API in interstate commerce and Amarin's products are marketed and sold in all states and territories of the United States. Drug wholesalers and, ultimately, patients across the country purchase Amarin's drugs, including Vascepa.

22. Defendants may be found in, transact business in, are headquartered in, and are subject to personal jurisdiction in the District of New Jersey.

23. This Court has subject matter jurisdiction based on 28 U.S.C. §§ 1331 and 1337(a), and 15 U.S.C. §§ 15 and 26. This Court has supplemental subject matter jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367(a).

24. This Court also has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a)(2) because there is diversity of citizenship between the parties and the amount in controversy exceeds $75,000, exclusive of costs and interest.

25. The violations of law alleged in this Complaint took place, in part, and have injured Apotex in this judicial district. Venue is therefore proper in the District of New Jersey pursuant to 15 U.S.C. §§ 15 and 22, and 28 U.S.C. § 1391.

STATEMENT OF FACTS

I. STATUTORY AND REGULATORY FRAMEWORK GOVERNING NEW AND GENERIC DRUG LAUNCHES.

A. New Drug Applications

26. The Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly known as the "Hatch-Waxman Act," requires Food and Drug Administration ("FDA") approval before a company may market or sell a branded or generic pharmaceutical product in the United States. The purpose of the Hatch-Waxman Act is to balance the preservation of brand pharmaceutical companies' incentives to innovate with the public interest in access to lower-cost, high-quality generic drugs through the creation of a carefully calibrated regulatory framework.

27. Manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application ("NDA"), which includes data regarding the safety and effectiveness of the drug product and information regarding applicable patents, including all patents covering the brand drug and such patents' expiration dates. When the FDA approves the NDA, it publishes the patent information in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations publication, also referred to as the "Orange Book." 21 U.S.C. § 355(b)(1) and (c)(2). The FDA does not substantively review the submitted patent information before publishing it.

28. The Hatch-Waxman Act provides manufacturers with certain market exclusivity periods to market and sell their drugs. For drugs involving "new chemical entities" ("NCE")—i.e., where the active pharmaceutical ingredient has not been previously approved for any other drug—the manufacturer is entitled to a five-year exclusivity period ("NCE exclusivity"). 21 U.S.C. §

355(c)(3)(E)(ii). For drugs involving new clinical studies leading to new or changed formulation, dosing regimens, or patient populations, the manufacturer is entitled to a three-year exclusivity period ("data exclusivity"). 21 U.S.C. § 355(c)(3)(E)(iii).

B. Generic Drug Applications

29. To achieve the goal of "get[ting] generic drugs into the hands of patients at reasonable prices – fast,"[5] the Hatch-Waxman Act provides for a streamlined approval process for generic drugs, whereby generic manufacturers may file Abbreviated New Drug Applications ("ANDAs") with the FDA. Unlike NDA filers, an ANDA filer need not conduct full clinical trials. Instead, an ANDA filer need only show that its drug is bioequivalent to the "reference listed drug," typically the brand drug, to demonstrate that the generic product has the same or comparable safety and efficacy as the reference listed drug.

30. Generic manufacturers are permitted to file their ANDAs one year before the expiration of the original manufacturer's NCE exclusivity period.

31. If an ANDA applicant seeks FDA approval to sell a generic drug before the expiration of the patents listed in the Orange Book as covering the drug, the ANDA must contain a certification that each of the relevant patents "is invalid or will not be infringed." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Such a certification is known as a "Paragraph IV Certification." The first filer of an ANDA for a product with a Paragraph IV Certification is entitled to 180 days of exclusivity from the first commercial marketing of the drug. 21 U.S.C. § 355(j)(5)(B)(iv)(I). If there are several first filers with the Paragraph IV Certification, the first filers all share the 180-day exclusivity.

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[5] *Andrx. Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (internal quotation marks omitted) (quoting *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991))

32. The filing of a Paragraph IV Certification may trigger the NDA-holders as well as the holder of any patent identified as purportedly covering the reference listed drug in the Orange Book to bring an action against the ANDA applicant for patent infringement. If such an action is brought within 45 days from the NDA holder's receipt of the Paragraph IV Certification notification, the FDA is precluded from granting final approval of the ANDA until the earlier of (i) 30 months from the NDA holder's receipt of the Paragraph IV Certification notification; or (ii) the date on which a final judgment is entered in the patent infringement case holding that such patent is invalid, not infringed, or unenforceable.

33. If an ANDA has satisfied all FDA regulatory requirements and the 30-month stay period has not expired or the ANDA applicant is otherwise prevented from launching because of patents, the FDA will grant tentative approval of the ANDA. The ANDA applicant may sell the generic product in the United States only upon receipt of final approval from the FDA, not upon receipt of tentative approval. Conversely, if the ANDA receives final approval, e.g. because the 30-month stay has expired, the ANDA applicant may immediately launch its generic drug regardless of the progress of the patent litigation. If the generic launches while the patent litigation, which may include the appellate process, is on-going, that launch is known as an "at risk" launch.

34. As an alternative to filing a Paragraph IV Certification, if the relevant patents cover only a specific use that the drug is approved for, the ANDA applicant may submit a "Section viii statement" that it is not seeking approval for the use claimed by the patents. 21 U.S.C. § 355(j)(2)(A)(viii). Such a statement is known as a "Section viii carve-out," and a generic drug label approved with a Section viii statement is known as a "carved out" or "skinny" label. Submitting an ANDA with a carved out label does not automatically trigger the patent litigation process described above, and the FDA may approve the carved out ANDA without having to wait. The legality of the FDA approving generic drugs with carved out labels has been upheld by the

courts. *See, e.g.*, *Sigma-Tau Pharms., Inc. v. Schwetz*, 288 F. 3d 141, 147-48 (4th Cir. 2002); *Bristol-Myers Squibb Co. v. Shalala*, 91 F. 3d 1493, 1500 (D.C. Cir. 1996).

C. Benefits of Generic Competition

35. Generic versions of branded drug products must contain the same API as the brand-name drug product and are determined by the FDA to be just as safe and effective as their brand counterparts. Because the branded drug product and its generics are therapeutically equivalent, the primary basis for competition between a branded product and its generic version, or between multiple generic versions, is price.

36. Generic drugs typically are sold at substantial discounts from the price of the brand drug. The first generic drug that enters the market generally is priced at a discount to the brand drug and, as additional generic drugs enter the market, generic drug prices may fall to as low as 5% of the brand drug's price. A 2017 study commissioned by the Association for Accessible Medicines ("AAM") found that while brand drug prices generally increased by over 200% between 2008 and 2016, generic drug prices generally decreased by approximately 75% during this period.

37. Without generic competition, branded drug product manufacturers can, and routinely do, sell their drug products for far more than the marginal cost of production, generating profit margins above 70%. When a generic equivalent enters the market, however, absent other market complexities, it often quickly captures 80% or more of the unit sales from the branded drug product. Over time, and with the addition of additional generics, this so-called generic penetration rate usually reaches 90% or more. When generic entry occurs, the branded drug product manufacturer loses most of the unit sales; the generic manufacturer sells most of the units but at reduced prices, delivering enormous savings to drug purchasers, insurance companies, and patients. When multiple generics compete in the market, that competition drives prices even lower.

38. Generic drug competition generates large savings for consumers and federal, state, and private payers. "Payers" include health plans and pharmacy benefits managers. A 2004 FDA study found that consumers whose needs can be fully satisfied with generic drugs could enjoy reductions of 52% in their daily medication costs. More recently, the 2017 AAM study found that generic drugs generated savings of $1.67 trillion for the U.S. health care system between 2007 and 2016.

D. Supply and Use of API in Drug Products

39. All drug products are made up of two core components: (i) the active pharmaceutical ingredient ("API"), which is the biologically active component of a drug product and its central ingredient, and (ii) the excipient(s), or other ingredient(s) that, although inactive, may perform a variety of other functional roles in the drug. The API is the part of the drug product that produces the intended effects. Excipients are chemically inactive substances in the drug product, such as lactose or mineral oil.

40. Brand and generic manufacturers ordinarily purchase the API for their drugs from API suppliers. The manufacturers combine the API with inactive ingredients and process the drugs into their final dosage form. The API for a brand drug and its generic equivalent is typically the same, and they may come from the same or different suppliers.

41. APIs are subject to stringent regulations and oversight by the FDA. To sell an API in the United States, the API supplier typically needs to file a Drug Master File ("DMF") with the FDA. The DMF provides confidential and detailed information about, among other things, the facilities and processes used to manufacture, process, package, and store the API.

42. In its application for FDA approval, a manufacturer must identify its API supplier and that supplier's DMF. More than one manufacturer can reference the DMF of the same API

supplier. As part of its review of an NDA or ANDA, the FDA performs a complete review of the technical information contained in the DMF referenced therein, including, among other things, inspecting the API supplier's facilities.

43. The entire process, from API development to FDA approval for use of that API supplier's DMF in support of an NDA or ANDA, ordinarily takes more than a year to complete, and can extend to as long as three years.

44. If a manufacturer wants or needs to change its API supplier for a drug, it must file a supplement with the FDA referencing the new API supplier's DMF and submit data for drug batches using the new supplier's API. The manufacturer may only market its drug using the new supplier's API if the FDA approves of the change. FDA review and approval of the change in API supplier can take 6 months or more from the time the new DMF is referenced in the NDA or ANDA. In addition to the six months or more it takes for FDA review and approval, this process takes at least 12 months of work on the manufacturer's end, including preparing samples, evaluating those samples, preparing batches, and putting the batches on stability. The process can take even longer when, as is the case here, the API is a natural product and thus contains a number of inherent impurities.

45. To avoid delays in the process and to keep costs lower, generic drug product manufacturers typically seek to use API from suppliers that already have a DMF on file, rather than partnering with API suppliers that have not yet filed a DMF. It is common for generic and brand manufacturers to use the same API supplier.

46. Generally, because of the significant costs involved in qualifying an API supplier as well as the need to continue to ensure quality control by the API supplier, it is industry practice for both brand and generic drug manufacturers to use only one or two API suppliers to support a drug application. It is unusual and contrary to industry practice for brand and generic

manufacturers to have multiple exclusive API supply contracts. Moreover, it is contrary to industry practice for brand and generic manufacturers to acquire significant excess API supplies due to, among other things, the costs of acquisition and storage as well as quality control issues.

II. VASCEPA

47. Vascepa is the brand name for Amarin's icosapent ethyl drug product. The API for the drug is eicosapentaenoic acid ("EPA" or "icosapent ethyl"), a type of omega-3 fatty acid derived from fish oil.

48. Amarin holds approved NDA No. 202057 for Vascepa. Vascepa is available in two strengths: 500 mg and 1 gram. There are currently two approved indications for Vascepa. The indications, dates of approval, and exclusivity periods are as follows:

Indication	**Description**	**Date of FDA Approval**	**Exclusivity Period**
"Very High TG Indication"	Can be used as an adjunct to diet to reduce TG levels in adult patients with severe (= 500 mg/dL) hypertriglyceridemia	July 26, 2012	NCE exclusivity until July 26, 2017
"CV Indication"	Can be used as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (= 150 mg/dL) and (i) established cardiovascular disease or (ii) diabetes mellitus and two or more additional risk factors for cardiovascular disease	December 13, 2019	Data exclusivity until December 13, 2022

49. Upon information and belief, Amarin has listed at least 61 different patents in the FDA Orange Book in connection with Vascepa. Of those 61 patents, Amarin caused several to be listed that relate to the Very High TG Indication, including, among others, U.S. Patent Nos. 8,293,728, 8,318,715, 8,357,677, 8,367,652, 8,377,920, 8,399,446, 8,415,335, 8,426,399, 8,440,650, and 8,518,929.

50. Amarin listed several other patents in the Orange Book relating to the CV Indication, including, among others, the 9,700,537, 8,642,077, and 10,568,861 patents.

51. Amarin currently markets Vascepa in the 1g and 500mg strengths. The list price for the drug as of September 2020 was $330.98 / 120 count for the 1g strength and $387.24 / 240 count for the 500mg strength. As the daily dose for Vascepa is 4g/day, this translates to $330.98/month for the 1g strength and $387.24/month for the 500mg strength.

52. Since it first received approval to market Vascepa, and in the absence of generic competition, Amarin has been steadily hiking the price of Vascepa. In particular, Amarin increased the price of Vascepa by approximately 51% from 2013 (when Vascepa price listing was first available) to 2017, with the list price in December 2017 at approximately $280/month. Between December 2017 and November 2019, the price increased by approximately 8% to $303.65/month for the 1g strength. Finally, in less than a year since the approval of the new indication, the list price for the 1g strength jumped by 9% to $330.98/month as of September 2020.

53. Vascepa is Amarin's only product, earning it over $427 million in net product revenue in 2019. Amarin's revenues have been growing dramatically over the years, as shown below. In July 2020, Amarin reported "Q1 2020 net total revenue of $155.0 million, [representing an] increase of 112% over Q1 2019."[6] Amarin reported net revenue for the sale of Vascepa in the United States in 2020 to be over $607 million,[7] and further believed that Vascepa total net revenue "will grow to reach multiple billions of dollars" beyond 2020.[8]

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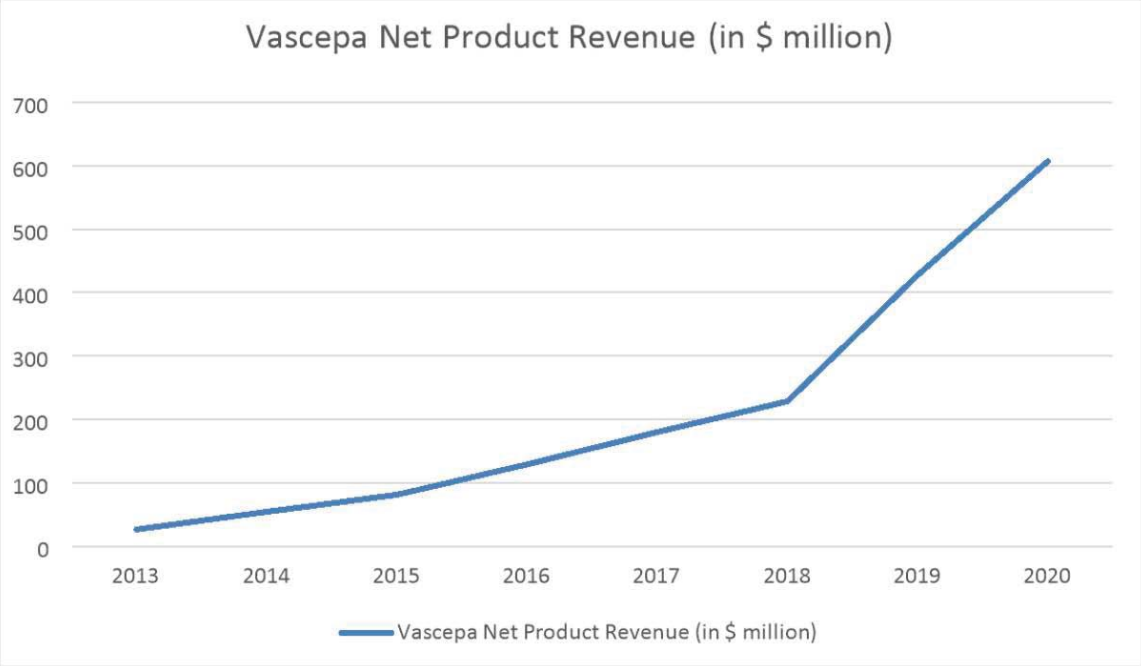
[6] Investor Presentation, Amarin Corp. plc, "Leading a New Paradigm in Cardiovascular Disease Management," at 17 (July 1, 2020).

[7] Amarin Corp. plc, Annual Report (Form 10-K), at F-5 (Feb. 25, 2021).

[8] Press Release, Amarin Corp. plc, "Amarin Receives FDA Approval of VASCEPA® (icosapent ethyl) to Reduce Cardiovascular Risk" (Dec. 13, 2019), https://www.prnewswire.com/news-releases/amarin-receives-fda-approval-of-vascepa-icosapent-ethyl-to-reduce-cardiovascular-risk-300974860.html#:~:text=Beyond%202020%2C%20Amarin%20believes%20that,annual%20revenue%20levels%20beyond%202020.



54. Clearly, the importance of Vascepa to Amarin cannot be overstated. As its president and chief executive officer stated in a company press release, "Amarin's goal is to protect the commercial potential of Vascepa to 2030."[9] And it endeavored to do just that through an anticompetitive strategy to lock up the supply for icosapent ethyl API to prevent generic competition, as described in more detail below.

III. AMARIN ENTERED EXCLUSIVE SUPPLY AGREEMENTS DESIGNED TO BLOCK COMPETITION.

55. Upon information and belief, Amarin entered into exclusive agreements with numerous API suppliers—including, but not limited to, KD Pharma, Nisshin Seifun Group Inc. ("Nisshin"), BASF SE (formerly Equateq Ltd.) ("BASF"), Chemport, Inc. ("Chemport"), Novasep Inc. ("Novasep"), and Slanmhor Pharmaceutical Inc. ("Slanmhor")—to maintain supply exclusivity and exclude or delay potential competitors from entering the market. This

[9] Press Release, Amarin Corp. plc, "Amarin Announces FDA New Chemical Entity Market Exclusivity Determination for Vascepa(R) (icosapent ethyl) Capsules" (May 31, 2016), https://investor.amarincorp.com/news-releases/news-release-details/amarin-announces-fda-new-chemical-entity-market-exclusivity.

anticompetitive conduct has allowed Amarin to maintain artificially high prices for its product and to delay, hinder, and frustrate robust generic competition.

56. Amarin entered into the first of these exclusive API supply agreements with Japan based Nisshin in November 2010. Upon information and belief, at the time Amarin contracted with Nisshin, Nisshin had an approved DMF to manufacture the API icosapent ethyl on file with the FDA, and Nisshin was the API supplier included in Amarin's NDA. The terms of that agreement prohibit Nisshin from selling API for commercial use to any competitor. Amarin initially purchased all its API needs from Nisshin.

57. Approximately four months later, in March 2011 (more than a year before Vascepa launched), Amarin signed a second exclusive supply agreement with Chemport. Upon information and belief, when Amarin contracted with Chemport, Chemport had an approved DMF to manufacture the API icosapent ethyl on file with the FDA. Like the Nisshin agreement, the Chemport agreement prohibited Chemport from supplying any competitors so long as Amarin met certain minimum purchase requirements. [10]

58. A mere three months later, in June 2011 (still well before Vascepa launched), the BBC reported that Amarin had entered into a third exclusive supply agreement with Scotland based Equateq Ltd. ("Equateq"). [11] Upon information and belief, when Amarin contracted with Equateq, Equateq had an approved DMF to manufacture the API icosapent ethyl on file with the FDA. Like Amarin's other agreements, Equateq was prohibited from supplying competitors if Amarin met minimum purchase requirements. Amarin revealed to investors in August 2011 that the minimum purchase commitment was intended to prevent Equateq from selling Vascepa API to any potential

[10] Amarin Corp. plc Quarterly Report (Form 15 10-Q), at 9 (Aug. 9, 2011).

[11] BBC News, *Drug firm Equateq secures big US order* (July 4, 2011), https://www.bbc.com/news/uk-scotland-scotland-business-14013747.

competitor of Amarin: "Following FDA approvals of [Vascepa], both agreements [with Equateq and Chemport] include annual purchase levels to enable Amarin to maintain exclusivity with each respective supplier, and to prevent potential termination of the agreements." [12] To lock in Equateq's exclusivity, Amarin also paid Equateq a $1 million "commitment fee" in May 2011. Equateq was acquired by BASF in May 2012. [13]

59. Six months later, in December 2012, Amarin announced it had entered into additional exclusive supply agreements with a consortium of companies led by Canada based Slanmhor that represented "the world's largest supplier of concentrated omega 3 fatty acid products." [14] Upon information and belief, when Amarin contracted with these companies, they had an approved DMF to manufacture the API icosapent ethyl on file with the FDA. Amarin explained that "Slanmhor, through exclusive agreements, is collaborating with [Royal DSM N.V.]/[Ocean Nutrition Canada] for the supply of intermediate omega 3 oil, and Novasep, a global leader in purification technologies and API manufacturing." [15] Together, Amarin said, the companies would work to "reliably source Vascepa." [16] At the same time, Amarin openly admitted that all its existing API needs for its expected launch of Vascepa would be "based on product produced by its existing API supplier, Nisshin." [17] Amarin's exclusive agreements with Equateq/BASF, Chemport, and the Slanmhor consortium explicitly locked up API supply that Amarin did not then, and would not foreseeably, need.

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[12] Amarin Corp. plc Quarterly Report (Form 10-Q), at 9 (Aug. 9, 2011).

[13] NUTRAingredients.com, *BASF completes omega-3 portfolio with Equateq buy* (May 8, 2012), https://www.nutraingredients.com/Article/2012/05/09/BASF-completes-omega-3-portfolio-with-Equateq-buy.

[14] Amarin Corp. PLC, "Amarin Announces Additional Vascepa(R) (Icosapent Ethyl) Supplier" (Dec. 11, 2012), https://amarincorp.com/news-and-media/amarin-announces-additional-vascepar-icosapent-ethyl-supplier.

[15] *Id.*

[16] *Id.*

[17] *Id.*

60. It was not lost on Amarin that, with the Slanmhor exclusive agreement, it had in essence cornered the market on API for Vascepa. In announcing the agreement, Amarin's then CEO and Chairman Joseph Zakrzewski boasted that the addition of "this exclusive Slanmhor consortium" to Amarin's existing supply bench meant that Amarin had succeeded in "[p]ooling the resources of four of the world's leading omega 3 API manufacturers" behind brand Vascepa—all before Amarin sold even a single pill. [18]

61. Because Amarin's 2012 FDA approval was based solely on Nisshin as its approved API supplier, Amarin had to seek supplemental approval from the FDA to use any of the three other API suppliers with whom Amarin had gratuitously entered into exclusive dealing arrangements. Having already secured a sufficient supply of API from Nisshin alone, Amarin did not rush to file supplemental new drug applications ("sNDAs") adding these suppliers.

62. In December 2012, Amarin finally submitted an sNDA for FDA approval to add Chemport as an API supplier—that application was submitted more than a year after Amarin had contracted with Chemport in March 2011. [19]

63. Tellingly, when announcing the Chemport sNDA, Amarin acknowledged that adding superfluous suppliers was part of its generic delay strategy, admitting that the "submission contributes to the planned expansion of the Vascepa manufacturing supply chain and is additional progress toward Amarin's goal to protect the commercial potential of Vascepa to beyond 2030 through a combination of patent protection, regulatory exclusivity, trade secrets and by taking

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[18] Fierce Pharma, *Amarin Announces Additional Vascepa(R) (icosapent ethyl) Supplier* (Dec. 13, 2012), https://www.fiercepharma.com/supply-chain/amarin-announces-additional-vascepa-r-icosapent-ethyl-supplier.

[19] Amarin Corp. PLC, *Amarin Announces Submission of Supplemental New Drug Application for Chemport, Inc. as an Additional Vascepa(R) Active Pharmaceutical Ingredient Supplier* (Dec. 19, 2012), https://amarincorp.gcs-web.com/static-files/98012da0-412f-4582-bfbe-21bba8c533fc.

advantage of manufacturing barriers to entry." [20] Amarin announced that the FDA approved the Chemport sNDA in April 2013 (two years after Amarin had contractually locked up Chemport).[21]

64. Similarly, Amarin entered into an exclusive supply agreement with BASF in June of 2011 but waited a year and a half to submit an sNDA for FDA approval to add BASF as an API supplier. [22] In its press release, Amarin doubled down on its disclosure that the acquisition of exclusive API supply agreements was intended to delay generic entry by "protect[ing] the commercial potential of Vascepa" and "taking advantage of manufacturing barriers to entry." [23] Amarin announced that the sNDA was approved on April 30, 2013 (nearly two years after contractually locking up BASF). [24]

65. Likewise, Amarin submitted an sNDA for FDA approval to add Novasep, (one of the companies in the Slanmhor consortium), as an additional icosapent ethyl API supplier in August 2013 (even though it had announced the Slanmhor agreement in 2012). The Novasep sNDA was likewise described as a way to "protect" Vascepa and utilize "manufacturing barriers to entry."

66. Amarin's delay in submitting sNDAs for each of these suppliers demonstrates the anticompetitive nature of the agreements. Amarin could not manufacture Vascepa using API from

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[20] *Id.* (emphases added).

[21] Amarin Corp. PLC, *Amarin Announces Approval of Supplemental New Drug Application for Chemport as Additional Vascepa® Active Pharmaceutical Ingredient Supplier* (Apr. 18, 2013), https://amarincorp.gcs-web.com/static-files/c822b3d2-72d5-49e2-a3a0-90d92854fb3f.

[22] Amarin Corp. PLC, *Amarin Announces Submission of Supplemental New Drug Application for BASF as an Additional Vascepa(R) Active Pharmaceutical Ingredient Supplier* (Jan. 2, 2013), https://www.globenewswire.com/en/news-release/2013/01/02/514184/18362/en/Amarin-Announces-Submission-of-a-Supplemental-New-Drug-Application-for-BASF-as-Additional-Vascepa-R-Active-Pharmaceutical-Ingredient-Supplier.html?print=1.

[23] *Id.* (emphasis added).

[24] Amarin Corp. PLC, *Amarin Announces Approval of Supplemental New Drug Application for BASF as an Additional Vascepa(R) Active Pharmaceutical Ingredient Supplier* (Apr. 30, 2013), https://investor.amarincorp.com/news-releases/news-release-details/amarin-announces-approval-supplemental-new-drug-application-basf.

these suppliers until the FDA approved the sNDAs. But, because Amarin had sufficient API supply already, without these additional suppliers, it was in no hurry to file the sNDAs. The agreements were intended to lock up the market, not to expand Amarin's API supply.

67. To incentivize suppliers to forego other opportunities, Amarin agreed to highly lucrative terms. Amarin's agreements with these API suppliers contain expensive minimum purchase requirements in exchange for exclusivity. For example, on information and belief, Amarin's minimum purchasing requirements with BASF cost Amarin between $10 and $20 million per year to maintain exclusivity.

68. Some of the agreements also require Amarin to make additional cash payments—beyond the minimum purchasing requirements—to lock in the suppliers' exclusivity. For example, in 2011, Amarin disclosed that, pursuant to its deal with Chemport, Amarin was required to "make minimum annual purchases from Chemport ranging from approximately $7.5 to $15 million" and "make a minority share equity investment in Chemport of up to $3.3 million." [25] Similarly, Amarin agreed to pay Equateq/BASF a one time $1 million commitment fee. [26]

69. Some of these agreements also include provisions that protect Amarin's exclusivity—and ensure that its competitors cannot access these suppliers—by requiring Amarin to make large cash payments in the event it does not satisfy the minimum purchase requirement for the suppliers. Amarin knew that it had locked up far more API supply than it would actually be willing or able to use in connection with its bona fide sales, so it had to agree to these naked payments in exchange for supply restrictions that would maintain its exclusivity and disadvantage its competitors.

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[25] Amarin Corp., *Amarin Announces Global Supply Network for AMR101* (May 31, 2011, 2:00 AM EDT) https://amarincorp.gcs-web.com/static-files/910a3e7f-c8d2-485c-a2f7-929c65b7e9db.

[26] Amarin Corp. plc Quarterly Report (Form 10-Q), at 9 (Aug. 9, 2011).

70. Amarin has no legitimate business justification for its collection of exclusive API supply agreements. Amarin started locking up API suppliers in 2011 before it had even begun recognizing revenue in 2014. And it reached exclusive supply agreements with five API suppliers before 2016, when it recognized only $81 million in sales. To maintain dominance over the icosapent ethyl API market, upon information and belief, Amarin made a concerted and continuing effort to keep its number of API suppliers higher than necessary to support its commercial needs. For example, when Amarin's exclusive supply agreement with BASF terminated in February 2014, Amarin entered into a new exclusive supply agreement with Finorga SAS (Novasep) in June 2015 and then yet another supply agreement with KD Pharma in December 2017. [27] There was (and remains) no legitimate reason for Amarin to obtain so many exclusive supply agreements when Amarin experienced no or very low demand for Vascepa at the time. And Amarin has never announced any supply issues with suppliers or publicly disclosed any other reasons why it would increase its API purchasing obligations so significantly.

71. Rather, the purpose of Amarin securing multiple exclusive API supply agreements was to foreclose future generic competition. Amarin did not hide the intent of these agreements: the purpose of the "minimum annual purchase levels [is] to enable [itself] to maintain certain supply exclusivity," rather than to ensure sufficient capacity to keep up with demand. [28] According to Amarin's then CEO, the company was making a concerted "effort to prevent a generic launch

[27] Amarin Corp. plc, Form 10-K (Mar. 1, 2017), available at https://www.annualreports.com/HostedData/AnnualReportArchive/a/NASDAQ_AMRN_2016.pdf; ECF No. 142 at 5, Dr. Reddy's Laboratories Inc. v. Amarin Pharms, Inc., 21-cv-10309 (ZNQ)(TJB) (D.N.J. Jan. 12, 2024).

[28] Amarin Corp. plc, Form 10-Q (September 30, 2018), *available at* https://www.sec.gov/Archives/edgar/data/897448/000156459018025979/amrn-10q_20180930 htm.

(if an ANDA approval is obtained)" and to erect artificial "barriers to competition" for generic competitors. [29]

72. Amarin actively tracked and reported to its investors on generic companies' unsuccessful efforts to obtain API supply. For example, John Thero, Amarin's then President and CEO boasted: "We have heard from various suppliers that they have been approached regarding supplying API for generic use. These suppliers informed us that they turned down such approaches[.]"[30] There would be no reason for Amarin to report to investors such feedback from suppliers except for the fact that it was part and parcel of Amarin's strategy to stymie competition, and that Amarin knew that reduced competition meant increased Amarin profits and share value, all at Apotex's, patients' and consumers' expense.

IV. AMARIN UNSUCCESSFULLY INITIATED PATENT LITIGATION TO PRECLUDE GENERIC MARKET ENTRY.

73. On July 16, 2016, Apotex filed its ANDA with the FDA, including a Paragraph IV Certification as to some, but not all of the patents then listed in the Orange Book for Vascepa. On that same day, Dr. Reddy's Laboratories Inc. ("DRL"), Teva Pharmaceuticals USA, Inc. ("Teva"), and Hikma Pharmaceuticals USA Inc. ("Hikma") submitted ANDAs for generic icosapent ethyl drug products, including Paragraph IV Certifications. These companies were the first ANDA filers with Paragraph IV Certifications for generic icosapent ethyl drug product.

74. Shortly after these ANDA applications were filed, Amarin initiated lawsuits against Teva, Hikma, and DRL, alleging that their respective ANDA products would infringe Amarin's

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[29] *Amarin Comments on Ruling in Vascepa® ANDA Litigation*, GlobeNewsWire (March 30, 2020), https://www.globenewswire.com/news-release/2020/03/30/2008763/0/en/Amarin-Comments-on-Ruling-in-VASCEPA-ANDA-Litigation html.

[30] Amarin Corporation plc Q1 2020 Earnings Call Transcript (April 13, 2020), *available at* https://www.fool.com/earnings/call-transcripts/2020/04/13/amarin-corporation-plc-amrn-q1-2020-earnings-call.aspx (emphasis added).

patents. Specifically, Amarin filed suit against Hikma on October 31, 2016, against DRL on November 4, 2016, and against Teva on November 18, 2016. Teva subsequently amended its ANDA to include a 500 mg generic version, and Amarin filed an additional lawsuit against it. These lawsuits were consolidated into a single action (the "Nevada Litigation"). Amarin did not file suit against Apotex.

75. On May 24, 2018, Teva and Amarin entered into a settlement agreement resolving the patent litigation against Teva's ANDA. Amarin's press release stated that the settlement agreement permitted Teva to launch its generic icosapent ethyl drug product on "August 9, 2029, or earlier under certain customary circumstances."[31]

76. On March 30, 2020, the District of Nevada ruled in favor of Hikma and DRL and issued an order invalidating Amarin's asserted patents for obviousness.[32] Amarin appealed the invalidity judgment to the United States Court of Appeals for the Federal Circuit ("Federal Circuit").

77. On May 21, 2020, the FDA granted final approval of Hikma's ANDA. On August 7, 2020, the FDA granted final approval of DRL's ANDA for its 1gram product (and tentative approval for its 500 mg product). On September 11, 2020, the FDA granted final approval of Teva's ANDA for both its 500mg and 1gram products.

78. On September 3, 2020, the Federal Circuit summarily affirmed the Nevada court's invalidity judgment.[33] Amarin requested a rehearing, but the Federal Circuit denied that request

[31] Press Release, Amarin Corp. plc, "Amarin Announces Patent Litigation Settlement Agreement with Teva" (May 24, 2018), https://investor.amarincorp.com/news-releases/news-release-details/amarin-announces-patent-litigation-settlement-agreement-teva.

[32] *Amarin Pharma, Inc. v. Hikma Pharm. USA*, 449 F. Supp. 3d 967 (D. Nev. 2020).

[33] *Amarin Pharma, Inc. v. Hikma Pharm. USA*, 819 F. App'x 932 (Fed. Cir. 2020).

as well. On February 11, 2021, Amarin petitioned for a writ of certiorari from the Supreme Court of the United States. The Supreme Court denied the request for certiorari June 21, 2021.

V. AMARIN SETTLED ITS PATENT INFRINGEMENT CLAIMS WITH APOTEX IN FURTHERANCE OF ITS ANTICOMPETITIVE SCHEME.

79. In May 2020, while Amarin's appeal of the Nevada Litigation was pending before the Federal Circuit, Apotex amended its ANDA and made a new Paragraph IV Certification as to all the patents covering the 2012 Very High TG Indication. Shortly thereafter, Amarin advised Apotex that it intended to assert its right to file suit alleging that Apotex's generic product infringed its Vascepa patents.

80. On June 16, 2020, Apotex and Amarin executed the Settlement Agreement, which resolved Apotex's patent infringement claims without resorting to litigation.

81. Pursuant to Section 4.1, [redacted]. Settlement Agreement, Section 4.2.

82. Amarin explicitly covenanted [redacted] Settlement Agreement, Section 5.2(c).

83. The parties also agreed to certain mutual releases and covenants not to sue. Section 2.2 of the Agreement provided that Apotex:

[redacted]

84. Pursuant to Section 5.1 of the Agreement, Apotex:

[redacted]

[34] The term [redacted] Settlement Agreement, Section 1.7.

[35] The term [redacted] Settlement Agreement, Section 1.9.

[36] The term [redacted] Settlement Agreement, Section 1.12.

85. The mutual releases and covenants not to sue in Sections 2.2 and 5.1(a) do not apply to or preclude the claims asserted in this action and cannot be enforced here at least because the claims did not [redacted]

86. Likewise, Section 5.1(b)'s covenant does not apply to or preclude the claims in this action and cannot be enforced here [redacted]

VI. AFTER EXECUTING THE SETTLEMENT AGREEMENT, AMARIN EXECUTED ITS PLAN TO FORECLOSE APOTEX'S ACCESS TO ICOSAPENT ETHYL API SUPPLY.

87. On June 30, 2021, the FDA granted final approval of Apotex's ANDA, at which point Apotex had cleared all regulatory, contractual, and patent hurdles to commercializing its icosapent ethyl products. However, in direct violation of the Settlement Agreement, Amarin nonetheless thwarted Apotex's efforts to launch.

88. As discussed above, Amarin engaged in a long-standing campaign to insulate Vascepa from competition by locking up icosapent ethyl API supplies. In furtherance of that scheme, Amarin conspired with KD Pharma to preclude Apotex from obtaining the API supply to which it was entitled pursuant to its existing agreement with KD Pharma.

A. Amarin Executed a 2017 Supply Agreement with KD Pharma to Preclude it from Supplying Amarin's Generic Competitors with API.

89. On information and belief, by as early as 2015, Amarin was aware that KD Pharma was preparing to supply API to generic manufacturers. To hinder potential competition, Amarin rushed to reach an agreement with KD Pharma to lock up its supply and ensure that it would be unable to meet the needs of generic manufacturers.

90. On information and belief, in December 2017, Amarin and KD Pharma entered into a supply agreement requiring KD Pharma to dedicate its entire API capacity to Amarin, despite the fact that Amarin did not require such capacity to manufacture its own product.

B. Apotex's Generic Launch Was Delayed by At Least Six Months Due to Amarin's Anti-Competitive Conduct.

91. On May 19, 2015, [redacted]

92. In June 2020, KD Pharma first took explicit steps to undermine Apotex's pending ANDA [redacted] Despite Apotex's [redacted], Apotex was unable to obtain API supply from KD Pharma in support of its ANDA. It is now obvious that the [redacted] was a pretextual cover for the continued implementation of the Amarin anticompetitive conspiracy. The timing of KD Pharma's effort [redacted] is particularly suspect, as it came only after Amarin's loss of the patent litigation against other generic manufacturers and only within the context of the Amarin-Apotex settlement.

93. As a result of KD Pharma's unjustified refusal to supply Apotex with the requisite API, Apotex was forced to submit a Prior Approval Supplement to the FDA on August 26, 2021, [redacted]. The FDA did not grant Apotex's request until December 14, 2021. Due to these delays, Apotex was unable to launch its generic product until December 2021.

94. There was no legitimate business reason for KD Pharma to refuse to supply Apotex, and this abrupt decision from KD Pharma to withhold its API supply caused an extraordinary hardship on Apotex, precluding it from commercially producing its approved ANDA product. KD Pharma's behavior makes no economic sense but for interference by Amarin.

95. Apotex was not the only generic manufacturer whose launch was stymied by Amarin's chokehold on KD Pharma's supply. On information and belief, DRL was similarly delayed in launching its generic product because KD Pharma refused to supply the necessary API, citing pretextual representations that it could not meet DRL's supply needs.

96. Upon information and belief, when DRL sought to obtain API for the launch of its generic product in 2020, KD Pharma represented that it was unable to fulfil DRL's orders due to lack of capacity. It was subsequently revealed that Amarin's agreement with KD Pharma contained stringent exclusivity requirements, and that Amarin had issued binding orders that blocked all of KD Pharma's capacity for icosapent ethyl. Such exclusivity requirements likewise impacted KD Pharma's otherwise inexplicable decision to refuse to supply Apotex under its supply agreement.

97. Accordingly, KD Pharma's refusal to work with Apotex to provide API supplies for a timely launch of Apotex's generic icosapent ethyl drug product was influenced by anticompetitive interference rather than legitimate business considerations.

98. But for Amarin's conduct, Apotex would have launched at least as early as when it received FDA approval in June 2021, and potentially earlier had the FDA approval not been delayed by the API supply issues resulting from Amarin and KD Pharma's then continuing anticompetitive conspiracy. Therefore, Amarin's various exclusive or de facto exclusive agreements, including its exclusive or de facto exclusive agreement with KD Pharma, delayed Apotex's launch of its generic icosapent ethyl drug product by at least six months and impacted the vigor of its entry even then with lasting injurious economic impacts.

MARKET SHARE EROSION AFTER GENERIC ENTRY

99. Not only did Amarin's conduct delay generic entry, but it also worked to inflate Amarin's market share even when generics finally entered the market.

100. For an uncomplicated product market like the icosapent ethyl market at issue here, it is typical for the branded drug product's share to quickly drop, and continue to drop further, as additional generic competitors enter.

101. But here, and even after two generic manufacturers entered the market, Amarin's chokehold on API supply allowed it to maintain roughly 80%–85% of the sales. And with four generic drug products on the market, at the end of 2023, Amarin has maintained approximately 57% market share.

102. This unusual behavior can only be explained by Amarin's exclusive API agreements and efforts to lock up icosapent ethyl API.

103. Amarin itself said that "[m]arket dynamics for payors and patients are likely to be unusual relating to these generic [Vascepa] products," pointing specifically to the anticipated "limited supply" of the generics.[37]

104. Indeed, in August 2020, as Amarin was anxiously awaiting the Federal Circuit's decision on its appeal of its trial loss to Hikma and DRL, Amarin's then CEO comforted his investors, stating that even if generics could find "supply capacity to support tens of millions of dollars in revenue [in the near term] . . . such level would only be a small portion of Amarin's total revenue and even a smaller portion of Vascepa's potential." [38]

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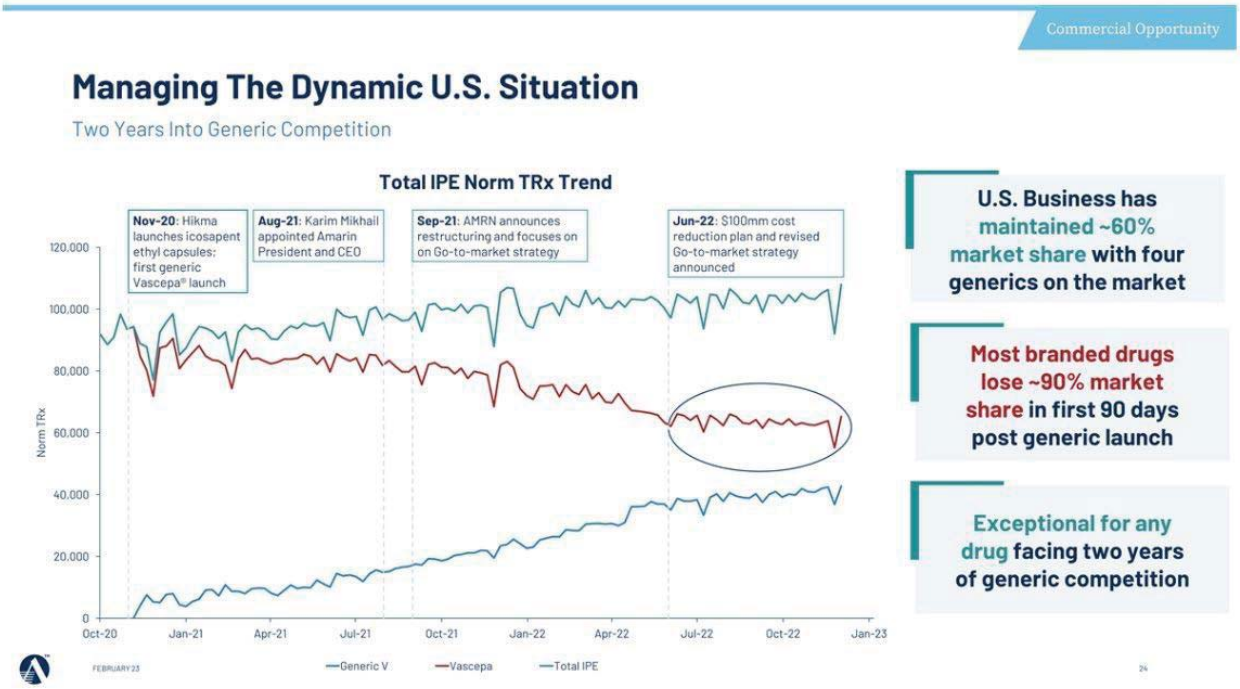
[37] Press Release, Amarin Corp. plc, "Amarin's Commercial Plans" (June 22, 2021), https://investor.amarincorp.com/static-files/21b859d2-0823-4fd5-9c14-91678feb8447 (emphasis added).

[38] Seeking Alpha, *Amarin Corporation plc's (AMRN) CEO John Thero on Q2 2020 Results – Earnings Call Transcript* (Aug. 4, 2020), https://seekingalpha.com/article/ 4364297-amarin-corporation-plcs-amrn-ceo-john-theroon-q2-2020-results-earnings-call-transcript.

105. And in a February 6, 2023 investor presentation, Amarin admitted that this trend of Amarin maintaining a large market share is "exceptional for any drug facing two years of generic competition." [39]



106. Amarin's enduring and "exceptional" market share, which persists to this date, is a result of its unlawful conduct in maintaining exclusive supply agreements that limited the supply of icosapent ethyl API.

107. Amarin's market share is also unusual for another reason. Since November 2020, at least four generics have launched at various times. However, the generic share of the market has not experienced any steep increases, as is usually the case upon generic entry in the absence of anticompetitive conduct.

108. The only explanation for this muted generic penetration is that generic companies have not been able to supply enough icosapent ethyl product to meet demand for its products, as a

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[39] Amarin Corp., Schedule 14A at 23 (Feb. 6, 2023), *available at* https://edgar.secdatabase.com/132/119312523025756/filing-main html (emphasis added).

result of Amarin's foreclosure of the icosapent ethyl API market. Rather, the generic share has only gradually increased over time as a result of generic companies' efforts to obtain more API supply.

109. But for Amarin's unlawful conduct, Amarin's market share would be lower and Apotex's and other generic's market share would be higher. And but for Amarin's unlawful conduct, Apotex would have been able to launch its generic product earlier into the marketplace and through earlier entry garner a more significant portion of the generic market share for its own sales, with lasting impact. Thus, to this date and beyond, Apotex's commercial sales and profits relating to its generic icosapent ethyl product continue to be constrained and frustrated because of Amarin's conduct.

MARKET POWER AND RELEVANT MARKETS

110. At all times Amarin has and has maintained monopoly power and market power in the markets for (i) FDA-approved icosapent ethyl drug product ("Icosapent Ethyl Drug Market"), which Amarin markets and sells as the brand product Vascepa (collectively "Icosapent Ethyl Drug Products"); and (ii) the purchase of icosapent ethyl API ("Icosapent Ethyl API Market"). Amarin's monopoly power and market power in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market include monopoly power and market power over any narrower markets therein.

111. Icosapent Ethyl Drug Products include AB-rated generic equivalents.

112. Amarin's monopoly power and market power include the ability to control prices and exclude competitors.

113. In the Icosapent Ethyl Drug Market, with respect to Amarin's ability to profitably raise prices, as shown above, a small but significant non-transitory price increase in the price of Vascepa has never resulted in a significant loss of sales, nor would a future small but significant

non-transitory price increase result in lost sales. In fact, despite Amarin's consistent price increases for Vascepa over the years, the demand for Icosapent Ethyl Drug Products continues to increase rather than decrease. With respect to Amarin's ability to exclude competitors, direct evidence demonstrates that generic versions of Icosapent Ethyl Drug Products would have more quickly entered the market at substantial discounts to the brand version but for Amarin's anticompetitive conduct.

114. Similarly, in the Icosapent Ethyl API Market, with respect to Amarin's ability to control prices, a small but significant non-transitory decrease in the purchase price of icosapent ethyl API does not and will not result in suppliers of icosapent ethyl API switching to the supply of a different API, including APIs for drugs in the same therapeutic class as Icosapent Ethyl Drug Products. With respect to Amarin's ability to exclude competitors, direct evidence demonstrates that Amarin, through several exclusive or de facto exclusive agreements, successfully precluded generic manufacturers of Icosapent Ethyl Drug Products, including Apotex, from purchasing sufficient icosapent ethyl API to commercially launch their generic icosapent ethyl drug products.

115. Amarin did not and does not need to control or influence pricing for any other pharmaceutical product to maintain its monopoly power and market power over Icosapent Ethyl Drug Products and the purchase of icosapent ethyl API.

116. Amarin has sold and continues to sell Icosapent Ethyl Drug Products at a price in excess of any measurement of competitive pricing and in excess of Amarin's marginal cost. Amarin has experienced atypically high profit margins for Icosapent Ethyl Drug Products, even now that multiple generic icosapent ethyl drug products have entered the market.

117. In addition to direct evidence of monopoly power and market power, indirect evidence also establishes monopoly power and market power. Icosapent Ethyl Drug Products exhibit high barriers to entry, including the costs of developing the product, patent protection, the

high cost of entry and expansion, regulatory requirements, and expenditures in marketing and physician detailing. Icosapent ethyl API similarly exhibits high barriers to entry, including the costs of developing the API, patent protection, the high cost of entry and expansion, and regulatory requirements.

118. Until November 2020, Amarin controlled 100% of the Icosapent Ethyl Drug Market. Even after Hikma launched with limited quantities in November 2020, due to the limited nature of the launch, Amarin's market share did not decrease significantly and remained above 85%. Surprisingly, Amarin's current market share is close to 60%. For example, Amarin's Chief Executive Officer commented that even if Hikma could find "supply capacity to support tens of millions of dollars in revenue [in the near-term] . . . such level would only be a small portion of Amarin's total revenue and even a smaller portion of Vascepa's potential."[40]

119. Similarly, until November 2020, Amarin controlled nearly 100% of the Icosapent Ethyl API Market because the volume of icosapent ethyl API that generic manufacturers used for their regulatory submissions is negligible compared to the commercial volume that Amarin purchased. Generics' inability to obtain sufficient API to support and maintain a more robust launch forced each to launch in limited quantities, gaining less than 40% of the of the icosapent ethyl Drug Market.

120. Icosapent Ethyl Drug Products are not reasonably interchangeable with any other drugs except for AB-rated generic versions of Icosapent Ethyl Drug Products.

121. Icosapent ethyl API is not reasonably interchangeable with any other API.

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[40] Seeking Alpha, *Amarin Corporation plc's (AMRN) CEO John Thero on Q2 2020 Results – Earnings Call Transcript* (Aug. 4, 2020), https://seekingalpha.com/article/4364297-amarin-corporation-plcs-amrn-ceo-john-thero-on-q2-2020-results-earnings-call-transcript.

122. The existence of other FDA-approved treatments for severe (≥ 500 mg/dL) hypertriglyceridemia has not significantly constrained Amarin, and Amarin has been increasing the prices for Vascepa over the years. For example, Lovaza is indicated for the reduction of triglyceride ("TG") levels in adults with severe (≥ 500 mg/dL) hypertriglyceridemia. Not only did Amarin not reduce the price of Vascepa upon the entry of generic omega-3-acid ethyl esters drug products in 2014, but it continued to increase Vascepa prices in the following years despite generic omega-3-acid ethyl esters drug products' price erosion over time. Even though Vascepa prices were and continue to be higher than the price of generic omega-3-acid ethyl esters drug products, demand for Lovaza and generic omega-3-acid ethyl esters drug products decreased over time whereas demand for Icosapent Ethyl Drug Products increased over time.

123. The existence of other purchasers of fish oil-based API has not significantly constrained Amarin, and Amarin has been maintaining exclusive or de facto exclusive agreements for the supply of icosapent ethyl API with the leading suppliers of fish oil-based API for several years.

124. Manufacturers differentiate brand drugs like Vascepa based on features and benefits (including safety and efficacy), and not based on price. Doctors and patients are generally price-insensitive when prescribing and taking prescription drugs like Vascepa. This is due in part to the presence of insurance that bears much of the cost of prescriptions and other institutional features of the pharmaceutical marketplace. Different patients may respond differently to different drugs and even drugs within its same therapeutic class do not constrain the price of Vascepa.

125. Unlike many consumer products where consumers are provided with a choice of functionally similar products at the point of sale and make purchasing decisions primarily based on price, the prescribing decision for prescription drugs is made by the prescriber, not consumers of these products.

126. The United States, and its territories, is the relevant geographic market.

ANTITRUST IMPACT

127. Amarin's anticompetitive strategy to maintain its monopoly in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market through exclusive or de facto exclusive agreements with at least five API suppliers, including KD Pharma, has and will continue to deny consumers the benefits of generic competition for Vascepa contemplated by the Hatch-Waxman Act. Amarin illegally maintained and extended its monopoly power through exclusionary conduct completely unrelated to its ability to compete on a level playing field.

128. Amarin's anticompetitive conduct has achieved its purpose of preventing and delaying generic competition to Amarin's Vascepa product. By engaging in this conduct, Amarin effectively foreclosed a substantial share of icosapent ethyl API supply. The lack of API supply delayed ANDA filers like Apotex from launching their generic icosapent ethyl drug product even though there was no legal or regulatory hurdle preventing launch.

129. This delay in competition is exactly what Amarin intended to, and did, cause through its unlawful conduct. As Amarin itself has explained, "if generic companies have limited supply capacity, it would be unusual for them to sell their limited supply at a low price as it would further strain their gross margins."[41] During these periods of delay, consumers were deprived of lower-priced generic icosapent ethyl drug product and forced to pay higher prices than they would but for Amarin's conduct.

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[41] Amarin Corp., *What is Amarin's plan for operations now that generic versions of icosapent ethyl have launched in the United States?* (June 22, 2021), https://amarincorp.gcs-web.com/static-files/b042df1f-bdf1-45bb-bbee-bb22a2a9b311#:~:text=In%20the%20United%20States%2C%20Amarin,to%20go%20to%20generic%20manufacturers.

130. Since generic drug products are therapeutically equivalent to brand name drugs, generic manufacturers compete by offering their drug products at lower prices. Drugs like icosapent ethyl have an uncomplicated distribution system in which entry of a single generic typically results in steep price reductions for purchases, and entry of several generics typically drives the price down close to marginal manufacturing costs. In a market unconstrained by supply issues, most branded drug products lose 82% of their market share within 12 months of generic launch due to substitution at the pharmacy level.[42] Automatic substitution practices allow pharmacies to fill prescriptions with generic drug products rather than branded drugs unless the prescribing physician specifically writes that a generic should not be substituted.

131. Amarin's foreclosure of the icosapent ethyl API Market, however, created a highly unusual circumstance for an otherwise uncomplicated market. By Amarin's own admission, "Amarin retained approximately 89% of the icosapent ethyl market in the first half of 2021, with approximately eight months of generic presence in the market.[43] And, by Amarin's own admission, this situation continued, and—rather than *losing* 82% of its market share, as would be expected with normal generic competition—"Amarin *retained* approximately 83% and 87% of the icosapent ethyl market in the three and nine months ended September 30, 2021, respectively, with approximately one year of generic presence in the market."[44] More recently, Amarin announced that in 2023, "the Amarin team continued to retain its [icosapent ethyl] market share leadership in

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[42] Grabowski, Henry, *Continuing Trends In U.S. Brand-Name And Generic Drug Competition*, JOURNAL OF MEDICAL ECONOMICS, Vol. 24 (July 5, 2021).

[43] Amarin Corp., *Amarin Reports Second Quarter and Six Month 2021 Financial Results and Provides Business Update* (Aug. 5, 2021), https://amarincorp.com/news-and-media/amarin-reports-second-quarter-and-six-month-2021-financial.

[44] Amarin Corp., *Amarin Reports Third Quarter 2021 Financial Results and Provides Business Update* (Nov. 3, 2021 6:00 AM EDT), https://amarincorp.com/news-and-media/amarin-reports-third-quarter-2021-financial-results-and-provides (emphasis added).

the U.S. at 57%," and that as it enters 2024, Amarin's "U.S. business continues to retain IPE market leadership."[45]

132. Amarin's anticompetitive conduct has had a direct, substantial, and adverse effect on Apotex and competition by monopolizing and maintaining monopoly power, artificially creating barriers to entry, and foreclosing competition in the icosapent ethyl Drug Market and icosapent ethyl API Market. But for Amarin's conduct, Apotex would have been able to obtain a sufficient supply of API to make a full-scale launch of its generic icosapent ethyl drug products upon or shortly after receiving final FDA approval, and would have obtained FDA approval earlier than June 2021.

133. Amarin's anticompetitive conduct has impeded and continues to impede the sale of generic icosapent ethyl drug products. Amarin's anticompetitive conduct impacted its generic competitors' pricing and market share and, therefore, stifled robust generic competition. Unless restrained by this Court, Amarin will continue to maintain and extend its monopoly power in the relevant markets and continue to sell Vascepa at artificially inflated monopoly prices.

134. This conduct has harmed the competitive process and allowed Amarin to perpetuate supracompetitive prices against wholesalers, retailers, patients and consumers. But for Amarin's anticompetitive conduct, consumers and federal, state, and private payors would have enjoyed the benefits of lower priced generic competition earlier. Instead, Amarin's strategies to thwart generic entry forced and continues to force consumers and federal, state, and private payors to pay monopoly prices for Amarin's branded Vascepa. The impact of Amarin's conduct is felt

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[45] Amarin Corp., *Amarin Provides Preliminary Fourth Quarter 2023 Selected Financials and Outlines Key Priorities for 2024* (Jan. 10, 2024), https://amarincorp.com/news-and-media/amarin-provides-preliminary-fourth-quarter-2023-selected.

throughout the healthcare industry, impacting pharmaceutical competitors, healthcare providers, insurers and direct purchasers, intermediaries, patients and consumers.

AMARIN'S CONDUCT HAS NO LEGITIMATE BUSINESS PURPOSE

135. There is no valid procompetitive business justification for Amarin's anticompetitive conduct, and even if Amarin offers one, it is pretextual and not cognizable, and any procompetitive benefits of Amarin's conduct do not outweigh its anticompetitive harms.

136. Amarin's multiple exclusive, or de facto exclusive API supply contracts have no legitimate procompetitive business purpose and are contrary to industry practice. It is industry practice for a manufacturer, including a brand manufacturer like Amarin, to have one or two API suppliers, even though more may be available, because it is costly and takes time and resources to qualify and ensure quality control at the API suppliers. It is also industry practice not to have exclusive agreements with multiple API suppliers for a single product. Thus, Amarin's agreements with at least five suppliers are contrary to industry practice and economically irrational. This indicates that Amarin entered into these exclusive or de facto exclusive agreements solely to prevent the suppliers from selling API to generic competitors, either through literal exclusivity or through buying up all available supplies.

137. Indeed, Amarin's several exclusive or de facto exclusive agreements with suppliers since 2012 cannot be justified by the usual rationale for manufacturers to enter exclusive supply contracts—i.e., to ensure adequate supplies. The additional exclusive contracts also cannot be explained by the 2019 indication or other market events.

138. Amarin has not been silent on its API supply. In fact, it has made repeated public statements about its API supply and the suppliers with whom it has entered agreements. Amarin never once mentioned a supply issue. Indeed, Amarin boasted about its abundant supply. Amarin's public statements in January 2018 confirmed that it had "capacity to provide supply to support the

potential of over $1 billion in product revenues in 2019." Accordingly, without any evidence of supply concerns, Amarin has no legitimate justification for entering into the exclusive or de facto exclusive agreements with suppliers.

139. And despite having an oversupply relative to its needs, Amarin has committed to paying suppliers to maintain exclusivity even when Amarin does not meet minimum purchase requirements. In a public statement, Amarin stated:

> We have agreements with API suppliers which include minimum purchase levels to enable us to maintain certain exclusivity with each respective supplier and certain agreements require any shortfall in such purchase levels to be paid in cash. [46]

140. Amarin's practice of agreeing to cover any shortfall in Amarin's minimum purchase commitments in cash payments is unnecessary given that Amarin faces no short or long run supply constraints on its access to icosapent ethyl. Rather, the true purpose for these agreements is made clear by Amarin's own public statements. In a public statement, Amarin said:

> [A]greements with our [API] suppliers include minimum purchase obligations and limited exclusivity provisions based on such minimum purchase obligations. If we do not meet the respective minimum purchase obligations in our supply agreements, our suppliers, in certain cases, will be free to sell the active pharmaceutical ingredient of Vascepa to potential competitors. Similarly, if we terminate certain of our supply agreements, such suppliers may be free to sell the active pharmaceutical ingredient of Vascepa to potential competitors of Vascepa. While we anticipate that intellectual property barriers and FDA regulatory exclusivity will be the primary means to protect the commercial potential of Vascepa, the availability of Vascepa [API] from our suppliers to our potential competitors would make our competitors' entry into the market easier and more attractive. [47]

141. As is clear from this statement, Amarin entered into exclusivity agreements and agreed to cover any shortfalls in its minimum purchase commitments with cash payments in order

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[46] Amarin Corp. plc Quarterly Report (Form 10-Q), at 40 (March 31, 2015).
[47] Amarin Corp. PLC, Annual Report (Form 10-K), at 40 (Feb. 27, 2014).

to constrain the availability of icosapent ethyl API supply to its competitors, with the explicit aim of deterring generic competitors from manufacturing and marketing generic icosapent ethyl drug products.

COUNT I

SHERMAN ACT SECTION 2 – MONOPOLIZATION

142. Apotex repeats each and every allegation of the preceding paragraphs as if set forth fully herein.

143. The Icosapent Ethyl Drug Market and Icosapent Ethyl API Market are the relevant markets.

144. Amarin possesses monopoly power in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market. These markets are characterized by significant barriers to entry.

145. This claim arises under the Sherman Act, 15 U.S.C. § 2, and the Clayton Act, 15 U.S.C. §§ 15, 26, and seeks a judgment that Amarin has violated Section 2 of the Sherman Act, 15 U.S.C. § 2, by monopolizing the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market.

146. Through the foregoing acts, Amarin, unlawfully and in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, has used, is using and, if not restrained by this Court, will continue to use, its power in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market to monopolize the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market.

147. Amarin knowingly and intentionally engaged in an anticompetitive strategy designed to unlawfully delay the launch of an AB-rated generic version of Vascepa, and thus to willfully maintain its monopoly power. Specifically, Amarin entered into exclusive or de facto exclusive agreements with at least four leading suppliers of icosapent ethyl API—BASF, Novasep, Chemport, and Nisshin—who are also the only suppliers with sufficient capacity to support a

timely commercial launch without having to first expand capacity. Further, Amarin entered into an exclusive or de facto exclusive agreement with KD Pharma, Apotex's existing icosapent ethyl API supplier, thus preventing KD Pharma from supplying to Apotex.

148. Amarin's conduct has no procompetitive, legitimate business justification. Amarin's conduct can only be explained by anticompetitive motives to foreclose competition in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market. For example, there is no legitimate business rationale for having four API suppliers, contrary to industry practice. Similarly, there is no legitimate business rationale for entering into ***exclusive*** agreements with five suppliers, as there is no indication of concerns with supplies. To the contrary, the evidence suggests that Amarin already had sufficient or an excess of API supply from its existing suppliers before entering into the agreement with KD Pharma, which alone covers nearly all the demand for the entire Icosapent Ethyl Drug Market. The only justification for these exclusive or de facto exclusive agreements is Amarin's intent to foreclose a substantial share of icosapent ethyl API supply and prevent generic competitors from launching their generic icosapent ethyl drug product.

149. To the extent there are legitimate business justifications for Amarin's exclusionary conduct, Amarin's anticompetitive conduct is not necessary to serve those justifications.

150. By its conduct, Amarin intentionally and wrongfully maintained monopoly power in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market in violation of Section 2 of the Sherman Act. As a result of Amarin's unlawful maintenance of monopoly power, Apotex has suffered and will continue to suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

151. Amarin's unlawful conduct as set forth above has the following effects, amongst others:

- Competition in the manufacture and sale of Icosapent Ethyl Drug Products was restrained, suppressed, and eliminated;
- Purchasers of Icosapent Ethyl Drug Products are deprived of the benefits of free and open competition, and the availability of a lower-cost generic icosapent ethyl drug product, in the purchase of Icosapent Ethyl Drug Products; and
- Amarin sold, and will continue to sell, its Vascepa at artificially high and noncompetitive price levels.

152. Amarin's conduct occurred in, and has had a substantial effect on, interstate commerce.

153. Amarin's anticompetitive and exclusionary conduct has directly and proximately caused injury to Apotex's business and property, as set forth above. Apotex's injury is the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

154. Amarin's unlawful conduct continues and, unless restrained, will continue. Thus, unless the activities complained of are enjoined, Apotex will suffer immediate and irreparable injury for which Apotex is without an adequate remedy at law.

155. Apotex is entitled to a judgment that Amarin has violated Section 2 of the Sherman Act; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to its costs and attorneys' fees; and to an injunction restraining Amarin's continued violations.

COUNT II

SHERMAN ACT SECTION 2 – ATTEMPT TO MONOPOLIZE

156. Apotex repeats each and every allegation of the preceding paragraphs as if set forth fully herein.

157. The Icosapent Ethyl Drug Market and Icosapent Ethyl API Market are the relevant markets.

158. Amarin possesses monopoly power in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market. These markets are characterized by significant barriers to entry.

159. This claim arises under the Sherman Act, 15 U.S.C. § 2, and the Clayton Act, 15 U.S.C. §§ 15, 26, and seeks a judgment that Amarin has violated Section 2 of the Sherman Act, 15 U.S.C. § 2, by attempting to monopolize the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market.

160. Through the foregoing acts, Amarin, unlawfully and in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, has used, is using and, if not restrained by this Court, will continue to use, its power in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market to attempt to monopolize the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market.

161. Amarin knowingly and intentionally engaged in an anticompetitive strategy designed to unlawfully delay the launch of an AB-rated generic version of Vascepa, and thus to willfully maintain its monopoly power. Specifically, Amarin entered into exclusive or de facto exclusive agreements with at least four leading suppliers of icosapent ethyl API—BASF, Novasep, Chemport, and Nisshin—who are also the only suppliers with sufficient capacity to support a timely commercial launch without having to first expand capacity. Further, Amarin entered into an exclusive or de facto exclusive agreement with KD Pharma, Apotex's existing icosapent ethyl API supplier, thus preventing KD Pharma from supplying to Apotex.

162. Amarin engaged in this conduct with the specific intent to monopolize the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market.

163. Amarin's conduct has no procompetitive, legitimate business justification. Amarin's conduct can only be explained by anticompetitive motives and a specific intent to foreclose competition in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market. For example, there is no legitimate business rationale for having four API suppliers, contrary to

industry practice. Similarly, there is no legitimate business rationale for entering into ***exclusive*** agreements with these five suppliers as there is no indication of concerns with supplies. To the contrary, the evidence shows that Amarin already had sufficient or an excess of API supply from its existing suppliers before entering into the exclusive agreement with KD Pharma. The only justification for these exclusive or de facto exclusive agreements is Amarin's specific intent to foreclose a substantial share of icosapent ethyl API supply and prevent generic competitors from launching their generic icosapent ethyl drug product.

164. To the extent there are legitimate business justifications for Amarin's exclusionary conduct, Amarin's anticompetitive conduct is not necessary to serve those justifications.

165. Amarin currently enjoys monopoly power in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market. There is a dangerous probability Amarin will succeed in gaining or maintaining monopoly power by means of its unlawful conduct, as shown by the fact that Amarin's conduct already delayed Apotex's launch of its generic icosapent ethyl drug product by at least 6 months.

166. By its conduct, Amarin intentionally and wrongfully attempted to maintain monopoly power in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market in violation of Section 2 of the Sherman Act. As a result of Amarin's unlawful attempted maintenance of monopoly power, Apotex has suffered and will continue to suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

167. Amarin's unlawful conduct as set forth above has the following effects, amongst others:

- Competition in the manufacture and sale of Icosapent Ethyl Drug Products was restrained, suppressed, and eliminated;
- Purchasers of Icosapent Ethyl Drug Products are deprived of the benefits of free and open competition, and the availability of a lower-cost generic icosapent ethyl drug product, in the purchase of Icosapent Ethyl Drug Products; and

- Amarin sold, and will continue to sell, its Vascepa at artificially high and noncompetitive price levels.

168. Amarin's conduct occurred in, and has had a substantial effect on, interstate commerce.

169. Amarin's anticompetitive and exclusionary conduct has directly and proximately caused injury to Apotex's business and property, as set forth above. Apotex's injury is the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

170. Amarin's unlawful conduct continues and, unless restrained, will continue. Thus, unless the activities complained of are enjoined, Apotex will suffer immediate and irreparable injury for which Apotex is without an adequate remedy at law.

171. Apotex is entitled to a judgment that Amarin has violated Section 2 of the Sherman Act; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to its costs and attorneys' fees; and to an injunction restraining Amarin's continued violations.

COUNT III

SHERMAN ACT SECTION 1 – CONTRACT, COMBINATION, OR CONSPIRACY IN RESTRAINT OF TRADE

172. Apotex repeats each and every allegation of the preceding paragraphs as if set forth fully herein.

173. The Icosapent Ethyl Drug Market and Icosapent Ethyl API Market are the relevant markets.

174. This claim arises under the Sherman Act, 15 U.S.C. § 1, and the Clayton Act, 15 U.S.C. §§ 15, 26, and seeks a judgment that Amarin has violated Section 1 of the Sherman Act,

15 U.S.C. § 1, by conspiring, combining and/or agreeing to restrain trade in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market.

175. Through the foregoing acts, Amarin, unlawfully and in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, has acted pursuant to a contract, combination, or conspiracy in order to, and with the likely effect of, unreasonably restraining trade in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market.

176. Amarin knowingly and intentionally engaged in an anticompetitive strategy designed to unlawfully delay the launch of an AB-rated generic version of Vascepa and thus protect itself from competition. Specifically, Amarin entered into exclusive or de facto exclusive agreements with at least four leading suppliers of icosapent ethyl API—BASF, Novasep, Chemport, and Nisshin—who are also the only suppliers with sufficient capacity to support a timely commercial launch without having to first expand capacity. Further, Amarin entered into an exclusive or de facto exclusive agreement with KD Pharma, Apotex's existing icosapent ethyl API supplier, thus preventing KD Pharma from supplying to Apotex.

177. Each of these agreements constitute contracts, combinations and conspiracies that substantially, unreasonably, and unduly restrain trade in the relevant markets, and harmed Apotex thereby.

178. Amarin's conduct has no procompetitive, legitimate business justification. Amarin's conduct can only be explained by anticompetitive motives and a desire to foreclose competition in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market. For example, there is no legitimate business rationale for having five API suppliers, contrary to industry practice. Similarly, there is no legitimate business rationale for entering into ***exclusive*** agreements with these five suppliers, as there is no indication of concerns with supplies. To the contrary, the evidence shows that Amarin already had sufficient or an excess of API supply from its existing

suppliers before entering into the agreement with KD Pharma, which alone covers nearly all the demand for the entire Icosapent Ethyl Drug Market. The only justification for these exclusive or de facto exclusive agreements is Amarin's desire to foreclose a substantial share of icosapent ethyl API supply and prevent generic competitors from launching their generic icosapent ethyl drug product.

179. To the extent there are legitimate business justifications for Amarin's exclusionary conduct, Amarin's anticompetitive conduct is not necessary to serve those justifications.

180. By its conduct, Amarin intentionally and unreasonably restrained trade in the Icosapent Ethyl Drug Market and Icosapent Ethyl API Market in violation of Section 1 of the Sherman Act. As a result of Amarin's unlawful contracts, combinations and conspiracies, Apotex has suffered and will continue to suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities.

181. Amarin's unlawful contracts, combinations and conspiracies as set forth above has the following effects, amongst others:

- Competition in the manufacture and sale of Icosapent Ethyl Drug Products was restrained, suppressed and eliminated;
- Purchasers of Icosapent Ethyl Drug Products are deprived of the benefits of free and open competition, and the availability of a lower-cost generic icosapent ethyl drug product, in the purchase of Icosapent Ethyl Drug Products; and
- Amarin sold, and will continue to sell, its Vascepa at artificially high and noncompetitive price levels.

182. Amarin's conduct occurred in, and has had a substantial effect on, interstate commerce.

183. Amarin's anticompetitive and exclusionary conduct has directly and proximately caused injury to Apotex's business and property, as set forth above. Apotex's injury is the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

184. Amarin's unlawful conduct continues and, unless restrained, will continue. Thus, unless the activities complained of are enjoined, Apotex will suffer immediate and irreparable injury for which Apotex is without an adequate remedy at law.

185. Apotex is entitled to a judgment that Amarin has violated Section 1 of the Sherman Act; to the damages it suffered as a result of that violation, to be trebled in accordance with the Clayton Act, 15 U.S.C. § 15, plus interest; to its costs and attorneys' fees; and to an injunction restraining Amarin's continued violations.

COUNT IV

THE NEW JERSEY ANTITRUST ACT, SECTIONS 56:9-3 AND 56:9-4

186. Apotex repeats each and every allegation of the preceding paragraphs as if set forth fully herein.

187. This claim arises under the New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9 et seq., and seeks a judgment that Amarin's conduct as alleged herein has violated New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9-4 and § 56:9-3.

Section 56:9-4, Monopolization

188. Amarin's conduct as alleged herein constitutes monopolization, attempted monopolization, and conspiracy to monopolize, in violation of N.J. Stat. Ann. § 56:9-4.

189. Specifically, Amarin's exclusive or de facto exclusive agreements with at least five leading suppliers of icosapent ethyl API—BASF, Novasep, Chemport, Nisshin, and KD Pharma—are calculated to maintain monopoly power in the relevant markets, in violation of N.J. Stat. Ann. § 56:9-4.

Section 56:9-3, Agreement in Restraint of Trade

190. Amarin's conduct as alleged herein constitutes a contract, combination, or conspiracy in restraint of trade or commerce, in violation of N.J. Stat. Ann. § 56:9-3.

191. Specifically, each of Amarin's exclusive or de facto exclusive agreements with at least five leading suppliers of icosapent ethyl API—BASF, Novasep, Chemport, Nisshin, and KD Pharma—is a contract, combination, and conspiracy in restraint of trade or commerce, in violation of N.J. Stat. Ann. § 56:9-3.

* * *

192. Amarin's unlawful contracts, combinations and conspiracies as set forth above has the following effects, amongst others:

- Competition in the manufacture and sale of Icosapent Ethyl Drug Products was restrained, suppressed, and eliminated;
- Purchasers of Icosapent Ethyl Drug Products are deprived of the benefits of free and open competition, and the availability of a lower-cost generic icosapent ethyl drug product, in the purchase of Icosapent Ethyl Drug Products; and
- Amarin sold, and will continue to sell, its Vascepa at artificially high and noncompetitive price levels.

193. Amarin's anticompetitive and exclusionary conduct has directly and proximately caused injury to Apotex's business and property, as set forth above. Apotex's injury is the type the antitrust laws are intended to prohibit and thus constitutes antitrust injury.

194. Amarin's unlawful conduct continues and, unless restrained, will continue. Thus, unless the activities complained of are enjoined, Apotex will suffer immediate and irreparable injury for which Apotex is without an adequate remedy at law.

195. Apotex is entitled to a judgment that Amarin has violated Sections 56:9-3 and 56:9-4 of the New Jersey Antitrust Act; to the damages it suffered as a result of that violation, to be trebled in accordance with N.J. Stat. Ann. § 56:9-12, plus interest; to its costs and attorneys' fees; and to an injunction restraining Amarin's continued violations.

COUNT V

COMMON LAW OF THE STATE OF NEW JERSEY – UNFAIR COMPETITION

196. Apotex repeats each and every allegation of the preceding paragraphs as if set forth fully herein.

197. By reason of the foregoing unlawful, predatory and anticompetitive acts as alleged herein, Amarin has engaged in unfair competition and/or unfair trade practices in violation of the common law of the State of New Jersey.

198. As a result of the foregoing, Apotex has been injured in its business and/or property and is entitled to damages, attorneys' fees, costs of suit and other appropriate relief.

COUNT VI

DECLARATORY JUDGMENT – SECTION 2.2

199. Apotex repeats each and every allegation of the preceding paragraphs as if set forth fully herein.

200. An actual controversy exists, within the meaning of 28 U.S.C. § 2201 and Fed. R. Civ. P. 57 between Apotex and Amarin regarding their respective rights and responsibilities under Section 2.2 of the Settlement Agreement.

201. Pursuant to Section 2.2 of the Agreement, [redacted]

202. Counts I to V of this action assert antitrust claims (the "Antitrust Claims") [redacted]

203. Nonetheless, Amarin may seek to file an action against Apotex erroneously asserting that Section 2.2 precludes Apotex's Antitrust Claims.

204. Therefore, to guard against the threat of suit by Amarin and injury resulting therefrom, Apotex requests that this court determine and declare the inapplicability of Section 2.2 to Apotex's Antitrust Claims.

WHEREFORE, Apotex requests that the Court enter a judgment in its favor and against Amarin as follows:

(a) Declaring that Section 2.2 of the Settlement Agreement does not apply to and does not preclude Apotex from asserting and pursuing its Antitrust Claims.

COUNT VII

DECLARATORY JUDGMENT – SECTION 5.1(a)

205. Apotex repeats each and every allegation of the preceding paragraphs as if set forth fully herein.

206. An actual controversy exists, within the meaning of 28 U.S.C. § 2201 and Fed. R. Civ. P. 57 between Apotex and Amarin regarding their respective rights and responsibilities under Section 5.1(a) of the Settlement Agreement.

207. Pursuant to Section 5.1(a) of the Agreement, [redacted]

[redacted]

208. The Antitrust Claims that [redacted]

209. Nonetheless, Amarin may seek to file an action against Apotex erroneously asserting that Apotex violated Section 5.1(a) by filing its Antitrust Claims.

210. Therefore, to guard against the threat of suit by Amarin and injury resulting therefrom, Apotex requests that this court determine and declare the inapplicability of Section 5.1(a) to Apotex's Antitrust Claims.

WHEREFORE, Apotex requests that the Court enter a judgment in its favor and against Amarin as follows:

(a) Declaring that Section 5.1(a) of the Settlement Agreement does not apply to and does not preclude Apotex from asserting and pursuing its Antitrust Claims.

COUNT VIII

DECLARATORY JUDGMENT – SECTION 5.1(b)

211. Apotex repeats each and every allegation of the preceding paragraphs as if set forth fully herein.

212. An actual controversy exists, within the meaning of 28 U.S.C. § 2201 and Fed. R. Civ. P. 57 between Apotex and Amarin regarding their respective rights and responsibilities under Section 5.1(b) of the Settlement Agreement.

213. Pursuant to Section 5.1(b) of the Settlement Agreement, [redacted]

214. The Antitrust Claims [redacted]

215. Nonetheless, Amarin may seek to file an action against Apotex erroneously asserting that Apotex violated Section 5.1(b) by filing its Antitrust Claims.

216. Therefore, to guard against the threat of suit by Amarin and injury resulting therefrom, Apotex requests that this court determine and declare the inapplicability of Section 5.1(b) to Apotex's Antitrust Claims.

WHEREFORE, Apotex requests that the Court enter a judgment in its favor and against Amarin as follows:

(b) Declaring that Section 5.1(b) of the Settlement Agreement does not apply to and does not preclude Apotex from asserting and pursuing its Antitrust Claims.

COUNT IX

BREACH OF CONTRACT

217. Apotex repeats each and every allegation of the preceding paragraphs as if set forth fully herein.

218. The Settlement Agreement is a valid and enforceable contract between Apotex and Amarin.

219. Apotex has performed and complied with all obligations under the Agreement.

220. Amarin breached the agreement through its anticompetitive efforts to prevent and delay Apotex's launch of its generic product.

221. Apotex suffered damages in the form of lost profits as a result of Amarin's breach of contract, as its product launch was delayed for at least six months with additional negative continuing economic impacts resulting thereafter.

JURY DEMAND

222. Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Apotex demands a trial by jury as to all issues of right to a jury.

PRAYER FOR RELIEF

WHEREFORE, Apotex respectfully requests that this Court enter judgment against the Defendants as follows:

a. Permanent mandatory injunctive relief pursuant to 15 U.S.C. § 26, Fed. R. Civ. P. 65, and N.J. Stat. Ann. § 56:9-10, restraining Amarin, its affiliates, successors, transferees, assignees and other officers, directors, partners, agents and employees thereof, from continuing, maintaining or renewing the conduct, contract, conspiracy, or combination alleged herein, or from engaging in any other conduct or entering into any other contract, conspiracy, or combination having a similar purpose or effect;

b. Compensatory damages for Apotex's lost sales of generic icosapent ethyl drug product, and profits on those sales, that are caused by Apotex's delay in launching its generic icosapent ethyl drug product;

c. Treble damages pursuant to 15 U.S.C. § 15 and N.J. Stat. Ann § 56:9-12;

d. Pre- and post-judgment interest as provided by law;

e. An award of attorneys' fee and costs pursuant to 28 U.S.C. § 15 and N.J. Stat. Ann. § 56:9-12; and

f. Such other and further relief as the Court deems just and proper.

Dated: June 14, 2024

BUCHANAN INGERSOLL & ROONEY PC

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